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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,490	09/10/2003	Robert B. DeVries	1001.1602101	3452

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EXAMINER	
LANG, AMY T	

ART UNIT	PAPER NUMBER
3731	

MAIL DATE	DELIVERY MODE
11/30/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/659,490	DEVRIES ET AL.	
	Examiner	Art Unit	
	AMY T. LANG	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-69* is/are pending in the application.

4a) Of the above claim(s) *11-64* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 65-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. **Claim 68** objected to because of the following informalities: lines 1-2 of the claim recite “of the composite elongated member” which should be replaced with “of the first composite elongated member.” Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. **Claim 67** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 67 first recites wherein the first end of the medical device and first composite elongated member are "in a first direction from the second end of the" medical device or first composite elongated member, respectively. However, it is unclear what is meant by "in a first direction." Does that infer they are on opposite sides of the device? Claim 66 also recites wherein "the axis of the first composite elongated member at the first end ... is offset from the axis of the composite medical device." However, it is unclear as to which axis is referred to.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claims 1-4, 6-10, and 65-69** are rejected under 35 U.S.C. 102(b) as being anticipated by Tomonto (US 6,425,855 B2).

With regard to **claims 1-4, 10, and 65**, Tomonto discloses a composite medical device (see entire document) having at least one elongate member, each strut (Figure 1). Each elongated member comprises an inner superelastic material (80) and an outer plastically deformable material (20, 30, or 40) (Figure 2; column 4, lines 20-50). Tomonto teaches the outer plastically deformable layer as sandwiching the inner superelastic material, which clearly overlaps the instantly claimed encasing (column 4, lines 52-56). Additionally, as shown in Figure 1, the outer layer is external to and directly attached to the inner layer on multiple sides so that the outer layer clearly surrounds the inner layer. The superelastic material is further disclosed as Nitinol, a shape memory alloy, and the plastically deformable material as stainless steel or titanium (column 4, lines 44-50). Therefore, the inner material is more elastic than the outer material. As shown in Figure 2, the medical device comprises at least one region of an exposed inner material where a portion of the outer material (20, 30, or 40) is vacant (column 5, lines 45-51). Therefore this region would inherently have increased flexibility.

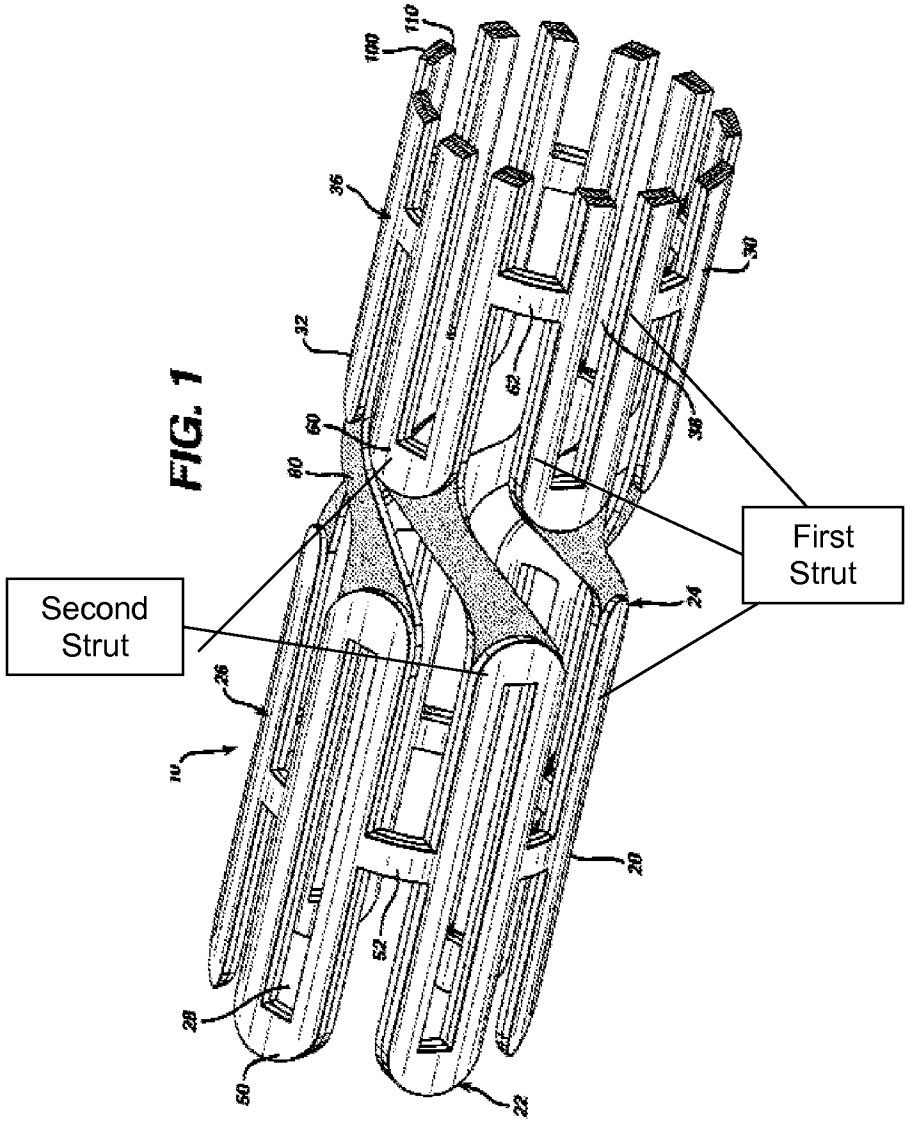
The composite medical device of Tomonto is a stent, which moves from a collapsed position to an expanded position at the target site. Since the inner layer of the stent comprises Nitinol, the inner layer biases the medical device to the expanded position (column 1, lines 43-60).

Additionally, as shown in Figures 1 and 3, the elongate members of the stent each comprise a solid cross-section along their entire length. Each strut is solid since it comprises the inner and outer layer without a gap between

With regard to **claims 6-8**, the limitations presented are product-by-process and therefore given no patentable weight. The determination of patentability in a product-by-process claim is based on the product itself, even though the claim may be limited and defined by the process. That is, the product in such a claim is unpatentable if it is the same as or obvious from the product of the prior art, even if the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 697, 227 USPQ 964, 966 (Fed. Cir. 1985). A product-by-process limitation adds no patentable distinction to the claim, and is unpatentable if the claimed product is the same as a product of the prior art. Once a device in the prior art has been found which is the same or substantially similar, it is encumbered upon applicant to show a non-obvious difference.

With regard to **claim 9**, it is the examiner's position that the stent of Tomonto overlaps the instantly claimed intravascular filter. When placed in a bifurcated vessel at the produced fork, the stent can act as a filter. Furthermore, merely calling the device a "filter" does not impart a structure to be patentably distinguished over the prior art.

With regard to claim 66, as shown below, Tomonto discloses more than one strut so that a first strut overlaps the claimed first composite elongated member and a second strut overlaps the claimed second composite elongated member. Every strut comprises the disclosed inner and outer layers.



With regard to **claims 67 and 68**, as shown in Figure 2, the medical device and first composite elongated member both comprise central longitudinal axes. Additionally,

the first ends of the device and first composite elongated member are both on opposite sides from second ends of the device and first elongated member. Lastly the longitudinal axis through the center of the medical device is offset from the longitudinal axis running through the first composite elongated member since the first composite member is located at the edge of the device. Therefore, the angle between these two axes is non-zero.

With regard to **claim 69**, both composite elongated members extend from the proximal end to the distal of the device so both extend in at least one direction the same, the claimed first direction (Figure 2).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. **Claim 5** is rejected under 35 U.S.C. 103(a) as being unpatentable over Tomonto (US 6,425,855 B2) in view of Moore (US 2004/0024444 A1).

Tomonto discloses a composite medical device comprising a stent having an inner superelastic material and an outer plastically deformable material. However, Tomonto does not specifically disclose the outer layer of the stent as coated with a polymeric layer.

Moore discloses a stent that preferably coated with a polymeric layer in order to minimize adverse interaction with the walls of the blood vessel or blood flowing through the vessel ([0064]). Therefore, it would have been obvious to one of ordinary skill at the time of the invention for the stent of Tomonto to comprise an outer polymeric coating for the advantages disclosed by Moore.

Response to Arguments

9. Applicant's arguments filed 07/29/2009 have been fully considered but they are not persuasive. Applicant argues that "any cross-section of Tomonto where an outer member surrounds and encases an inner member is hollow, not solid." The Examiner is not quite sure what is meant by this argument but Applicant references Figure 3 of Tomonto to show a hollow member. However, as explained above, each elongated member of the stent of Tomonto comprises a solid strut. Therefore, Tomonto does teach multiple solid elongated members.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMY T. LANG whose telephone number is (571)272-9057. The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

11/23/2009
/Amy T Lang/
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
11/25/09